

Radiation Safety Committee	Human-Use Protocol Review
Standard Operating Procedure	

Background	<p>The Radiation Safety Committee (RSC) is required to review and approve all uses of radioactive materials or exposure to ionizing radiation in human subjects. The RSC has established a Human and Non-Routine Protocol Review Subcommittee whose members have the appropriate technical expertise to review protocols and make approval recommendations to the RSC. RSC protocol approval is in addition to protocol approval by the USDA Human Studies Review Committee.</p>
Overview of Human-Research Committees	<p>Prior to the initiation of research involving human studies, researchers must gain approval from several oversight committees at the local and federal levels. For research involving radioisotopes or ionizing radiation the following human-use committees may be involved in protocol approval:</p> <p>Local Oversight:</p> <ul style="list-style-type: none"> • Institutional review board • Radioactive Use Review Committee (if applicable) <p>USDA Oversight:</p> <ul style="list-style-type: none"> • ARS Human Studies Review Committee • Radiation Safety Committee <p>USDA Oversight</p> <p>Agricultural Research Service (ARS): The ARS is the only USDA Agency that conducts human research. ARS has implemented Directive no. 605.1 "Protection of Human Subjects" that details ARS policy and outlines steps that an investigator must follow when proposing research involving human subjects. Title 45 CFR, Part 46: "Protection of Human Subjects" is attached to the directive and the investigator must follow the guidance in that document. This Committee is charged with "ascertaining the acceptability of the proposed research in terms of ARS's commitments and regulations, applicable law and standards of professional conduct and practice." Approval by the Human Studies Review Committee is required before any human studies can begin and without approval from this committee, research with human subjects may not be initiated.</p>
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<p>Overview of Human-Research Committees (cont.)</p>	<p>Radiation Safety Committee</p> <p>Human and Non-Routine Protocol Review Subcommittee: The RSC has established this Subcommittee to review Human and Non-Routine Protocols and make approval recommendations to the RSC. This committee is composed of the USDA Radiation Safety Officer; Chair of the RSC; and Technical Representatives for Animal, Human, and Biotechnology Research. Review by this Subcommittee is limited to compliance with the USDA's broad scope license conditions. The review is not a technical evaluation of radiation dose to human subjects or an assessment of the appropriateness of the human-use protocol.</p> <p>USDA Radiation Safety Staff: The RSS is responsible for reviewing human-use protocols to ensure that adequate dose evaluations were made and that adequate radioactive materials control and security procedures will be followed.</p> <p>Local Oversight</p> <p>Institutional Review Board and(or) Radioactive Research Committee: The human use research protocol must be reviewed and approved by a local Institutional Review Board or, if applicable, by the local Radioactive Use Committee.</p>
<p>Protocol Approval Process</p>	<p>1. Permit Holder The Permit Holder obtains approvals from:</p> <ul style="list-style-type: none"> • Institutional Review Board and(or) Radioactive Use Committee • USDA Human Studies Review Committee and submits the protocol and approvals to the RSS <p>NOTE: The RSC and Human Studies Review Committee can review protocols concurrently. The RSC can approve radioisotope use pending approval of the Human Studies Committee, and vice versa.</p> <p>2. Radiation Safety Staff</p> <ul style="list-style-type: none"> • The RSS obtains all safety information or approval documentation (if needed) • The RSS sends protocol and other relevant documentation to the Human and Non-Routine Protocol Review Subcommittee
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Protocol Approval Process (cont.)	3. Human and Non-Routine Protocol Review Subcommittee <ul style="list-style-type: none"> Subcommittee reviews the protocol Members send a signed approval/rejection form to RSS 4. Radiation Safety Staff <ul style="list-style-type: none"> The RSS sends a letter to the permit holder indicating whether the Subcommittee approved the protocol The RSS amends the permit to include approved protocol materials and documents

Approved:

<div style="border-top: 1px solid black; margin-top: 80px; text-align: center;"> Chair, Radiation Safety Committee </div>	<div style="border-top: 1px solid black; margin-top: 80px; text-align: center;"> Date </div>
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